I. Remarks

Claims 1-3, 14-18 and 46-48 are pending in this application. New Claims 49-58 are added herein.

Claims 4, 6-7, 9-10, 12-13, 23-24, 26-27 and 32-33 were cancelled in Applicant's Response dated 12/26/2006 and Claims 19-22, 25, 28-31, and 34-45 were cancelled in Applicant's Response dated 03/26/2008. Claims 5, 8, and 11 are cancelled herein.

The cancellation of the aforementioned claims should not be construed as an abandonment of the subject matter covered by the cancelled claims. Applicant reserves the right to file one or more divisional applications directed to the cancelled subject matter.

Support for the newly added claims is shown in the following Table:

Claim No.	Supported in the Specification
49	[0058]
50	[0058]
51	FIG. 3
52	[0040-[0045]
53	[0040-[0045]
54	[0040-[0045]
55	[0036]
56	[0049]
57 & 58	[0036] & original Claim 12

Accompanying this Response is a Petition for Extension of Time (PTO/SB/22) for a 1-month extension of time as well as the required fee.

II. Rejection Under 35 U.S.C §102(b)

Claims 1-3, 8, 14-18, and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Stasz (US Patent 5311875).

A. Rejection of Claim 1

As to Claim 1, Examiner contends that Stasz reference discloses a sensor comprising a flexible substrate (12), a flexible transducer (10), first and second electrical contacts (22 and 24), protective covering (14 and 16), at least one flexible lead (32).

As taught by the Stasz reference, the flexible substrate e.g., KYNAR (polyvinylidene fluoride) is a material that exhibits both piezoelectric and pyroelectric properties making the film useful in dynamic film transducers. (Col.3, lines 1-62). Structures (14) and (16) of the reference are not "protective coverings" but are areas of the piezoelectric/pyroelectric film (12); structure 14 is one surface and 16 is the opposed surface. Structures 22, 24, and 26 are not "electrical contacts" as is asserted by Examiner but are areas of the transducer that are inserted into the nostrils (22 and 24) and a flap which projects over the mouth (26). Structure (32) is an "elongated tail section" of the film (12) which contains areas of metallization (34 and 36) on both sides.

There are key differences between the sensor claimed by Applicant and the sensor/transducer claimed by Stasz. The flexible substrate used by Applicant is required to be non-conductive. In contrast, the film substrate utilized by Stasz must exhibit pyroelectric and piezoelectric properties. Stasz teaches that polyvinylidene fluoride (PVDF) is particularly useful.

The sensor of Stasz must have a layer of metallization over the major portion of the PVDF film. Stasz teaches (Col. 3, lines 37-41) that while the entire PVDF film serves as a substrate, only those portions sandwiched between the metallized portion contributes to the voltage developed due to temperature shifts or applied force changes. There is no layer of metallization in the sensor claimed by Applicant.

Claim 1 of Stasz requires the transducer to be adapted to be disposed relative to the respiratory passages of a human or animal in order to intercept the flow of respiratory gases exiting such passages. Clearly, the sensor of Stasz functions to detect exhaled breaths of a human or animal. In contrast, if the sensor of Applicant is used in a hand-held, breath-actuated electrohydrodynamic aerosolization device, in order to deliver a medicament to a human, the sensor is positioned in the device to react to ambient air drawn into the device by the inhalation of the user. The sensor of Applicant when disposed in a hand-held EHD aerosolization device never comes in contact with the breath of the user as either an expired or inspired breath.

The flexible PVDF film substrate of Stasz produces a low frequency output voltage signal proportional to changes in temperature due to the impingement of respiratory gases thereon (Claim 1). The area of metallization on the PVDF film acts as an electrode to conduct the voltage to the electrical connector (42) and then through wires (44 and 45) to the circuit means described in FIG. 4 and Fig. 5. Stasz describes and claims a transducer which must have 2 elements in order to function as required. The first element is the PVDF film which produces a voltage signal proportional to changes in the temperature of respiratory gases and the second element is the layer of metallization which acts as an electrical conductor to convey the voltage to a circuit means. In Applicant's invention, the voltage signal is produced by the bending or flexing of the resistive ink transducer not the film substrate.

The "flexible lead" structure (16) described by Applicant in Figs. 1A to 1C, is not the same as the "elongated tail" of Stasz which is electrically connected to electronic circuitry. The flexible lead is a continuation of the non-conductive flexible substrate (12). At least one flexible lead (16) hingedly connects inlet-covering portion (14) to mounting portion (18) of sensor (10). The flexible leads are adapted to allow the inlet-covering portion (14) of the sensor to flex easily when impinged upon by flowing gas or liquid.

B. Rejection of Claims 2 & 3

Claim 2 and Claim 3 are rejected over Stasz on the ground that the reference discloses a protective covering that substantially covers the flexible transducer and the first and second contacts.

The Stasz reference describes a film covering (30) overlayed on the metallized portion of the PVDF film substrate. All that the reference says about this film covering is that it is a "non-porous film layer" (Col. 3, line 48). Since the reference gives no guidance about the other properties of this film, it is impossible to determine if this film is equivalent to the non-conductive film overlaying Applicant's transducer which is required to be a non-conductive material and which does not exhibit a memory when bent [0036]. Claim 2 and claim 3 of Applicant depend from Claim 1 and for the reasons discussed above, Claim 1 is not anticipated by the Stasz reference; accordingly, neither are Claims 2 & 3.

C. Rejection of Claim 5

Claim 5 is cancelled herein; accordingly, Examiner's rejection of this claim is mooted.

D. Rejection of Claim 8

Examiner rejects Claim 8 of Applicant's claimed invention contending the following:

> Stasz discloses the flexible substrate to have a first and second side (18 & 20), the first and second contacts being affixed to the first side of the substrate, the third contact (36) is affixed to the second side of the substrate and is in communication with the first electrical contact (22) and the fourth contact (34) is affixed to the second side of the flexible substrate and is in communication with the second electrical contact (24); wherein the first and third contacts are in communication and the second and fourth contacts are in communication.

Referring to Fig. 2 of Stasz, the flexible substrate 12, i.e., the PVDF film, has a layer of metallization 18 & 20 on each side. The first and second sides of the flexible substrate are not labeled 18 and 20 in Fig. 2 but are labeled 14 and 16. As previously discussed, structures 22, 24 and 26 of Fig. 1 of Stasz reference are not electrical contacts. These structures are lobes of the sensor that are inserted into the patient's nose are (22 & 24) and over the patient's mouth (26). When the patient's expired breath falls on these parts of the transducer portion of the Stasz sensor the a voltage develops due to temperature shifts or pressure changes that is relayed through the tail portion of the Stasz sensor which is inserted into an electrical connector (42 in Fig. 3) which mates with conventional wires 44 ad 46.

Applicant's new Claim 56 which replaces old Claim 8 describes a third and fourth electrical contact (26c and 26d) on the second side of the flexible substrate, in which the third electrical contact is in electrical contact with the first electrical contact (26a) and the fourth electrical contact (26d) is in contact with the second electrical contact (26b). There is nothing in the Stasz reference which describes these electrical contacts.

E. Rejection of Claim 11

Claim 11 is rejected on the grounds that Stasz discloses an "air inlet" portion and that Fig. 3 discloses this inlet portion. Claim 11 is cancelled herein; accordingly, the rejection is obviated.

F. Rejection of Claim 14

Claim 14 is rejected over Stasz, on the grounds that the reference discloses contacts (22 and 24) that are affixed to a mounting portion (28).

As argued above, nothing in Stasz describes electrical contacts that are equivalent to those (see Fig. 1B structures 26a and 26b) in the sensor of Applicant. The structure in the Stasz reference that Examiner calls a "mounting portion" is actually a pressure sensitive adhesive for sticking (affixing) the Stasz sensor in the nares and on the skin of the patient. Unlike the sensor of Stasz, the sensor disclosed by Applicant is not stuck to the skin of a patient nor does it have to be in contact with a patient to be useful.

The mounting portion (18) of Applicant's sensor is a continuation of the film substrate (13). The mounting portion of the sensor is adapted to be removably secured to a mounting point of something, e.g., a hand-held aerosolization device, such that inlet portion (14) is located proximate to an air inlet. The inlet-covering portion of the sensor is adapted to be positioned proximate to an air-inlet so as to effectively block the inlet when air is not flowing.

G. Rejection of Claims 15-16

Examiner rejects Claims 15-16 on the grounds that Stasz discloses that the electrical value of his transducer changes in proportion to the flexure of the substrate and that the value increases as the substrate is flexed. This statement is incorrect.

The transducer described by the Stasz reference detects changes in temperature and pressure. It is not required to bend or flex in order to detect a change in temperature or the pressure of a patient's breath impinging on the sensor. Examiner points to Col. 3, lines 9-19 as supporting his assertion; these lines read as follows:

> "Typical of such films are those made from polyvinylidene fluoride (PVDF), that material being sold under the registered trademark, KYNAR, by the Pennwalt Corporation. This film material possesses dynamic characteristics. That is to say, it develops an electrical charge proportional to changes in mechanical stress or strain imposed on it. It also acts as a pyroelectric dynamic device developing an electrical charge proportional to temperature changes to which the film is exposed."

There is nothing in this language, which indicates that the transducer of Stasz develops an electrical charge proportional to the bending or flexing of the transducer.

Examiner's attention is directed to Col. 3, lines 34-41 where it is taught that:

> "The zones of sensitivity of the transducer are those that include overlapping metallization on the opposed major surfaces. Thus, while the entire KYNAR film serves

> as a substrate, only those portions effectively sandwiched between the metallized electrodes contribute to the voltage developed due to temperature shifts or applied force changes. [emphasis added]

Directly applying pressure to the surface of the transducer of Stasz to produce a voltage change is not the same as producing a voltage due to breaking or cracking of a resistive ink transducer by flexing or bending the sensor.

H. Rejection of Claim 17

Claim 17 is rejected on the grounds that Stasz discloses a flexible substrate made of polyimide. This is not a fair reading of Stasz. The reference teaches that polyvinylidene fluoride (PVDF) may be used as the substrate in the transducer of Stasz. PVDF is not a polyimide. PVDF develops a charge proportional to changes in temperature and pressure. Those skilled in the art would not equate the PVDF film used by Stasz with the non-conductive polyimide films used by Applicant in the sensors of his invention.

I. Rejection of Claim 18

Examiner rejects Claim 18 on the grounds that the sensor of Stasz is placed in the nares of the patient and thus is positioned in a stream of moving air. Stasz does disclose that the sensor of Stasz is adhered to the nares of a patient and that the patient breathes in and out over the sensor. However, Applicant's Claim 18 is directed to a sensor according to Claim 1 wherein the sensor forms at least a portion of a one-way valve in a stream of moving gas. There is nothing in Stasz that indicates that the sensor of Stasz forms a one-way valve.

J. Rejection of Claims 46 & 47

Claims 48 and 47 are rejected over Stasz on the grounds that Stasz discloses a transducer (10) affixed to a lead (32).

Structure 32 of Fig. 1 of Stasz is an elongated tail section of the sensor which has conductive strips (layer of metallization) on opposed surfaces separated by a layer of insulation. The elongated tail section where there is a layer of metallization mates with an electrical connector (42).

Referring to Fig. 1B of Applicant, the flexible lead (16) is an extension of the non-conductive film (13). Both structures 16 and 13 have printed thereon a strip of resistive ink which is the transducer (22) portion of the sensor. The resistive ink (22) is on one side only of the non-conductive film and both ends connect with the electrical contacts (26a) and (26b).

Stasz does not anticipate Applicant's Claims 47 and 48 because these claims do not cover subject matter which is the same as "an elongated tail segment 32 having the conductive strips 34 and 36 on opposed major surfaces thereof wherein a slit 38 is made through the thickness dimension of the film 12 to facilitate folding of the terminal portion 40 so that when so folded, the metallization on opposed sides of the strip will be aligned with one another but separated by a layer of insulation such that the folded end segments of the tail 32 can be readily inserted into an electrical connector 42 to mate with conventional wires".

III. Analysis

In order to "anticipate" an invention a prior art reference must disclose to one of ordinary skill in the art all elements and limitations of the patent claim. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (1991). If the prior art reference lacks an element of a claim at issue, it can not anticipate. See *Al-Site Corp v. Opti-Ray Inc.* 28 USPQ2nd 1915, 1920 (E.D. N.Y. (1993).

The Stasz reference does not anticipate any of Applicant's claims because the sensor/transducer described by Stasz comprises a piezoelectric/pyroelectric sensor while the sensor claimed by Applicant is a flex or bend sensor containing a resistive transducer. The resistive transducer used in Applicant's invention is not the same as the piezoelectric/pyroelectric transducer used in the sensor of Stasz. A resistive transducer works not by the detection of pressure or temperature, but by providing a signal related to the amount of angular displacement of the body (12) to which it is attached. One skilled in the art would not consider the sensors to be the same.

Claim 1 of Stasz requires a flexible polyvinylidene substrate which must exhibit piezoelectric and pyroelectric properties. In contrast, the flexible substrate of Applicant's sensor must be non-conductive and does not exhibit pyroelectric or piezoelectric properties.

The transducer element of Applicant's sensor, does not detect thermal changes because it is not pyroelectric; therefore, it does not produce a low frequency output voltage signal proportional to changes in temperature as is required by Stasz.

The transducer of Stasz is multilayered and is composed of a piezoelectric film substrate having a pattern of flexible metallization on each side of the film substrate. A layer of insulation covers each layer of metallization on each side of the flexible substrate. The layer of metallization is present on both sides of the film substrate and is required for voltage development due to temperature shifts or applied force changes. In contrast, the transducer element of Applicant's sensor is a layer of resistive ink that is printed

or deposited on the component side of the non-conductive flexible substrate (13). Applicant's transducer is not multilayered nor is any metallization present on the transducer element of Applicant's sensor.

When the transducer element of the Stasz sensor (Fig. 2) is compared to the transducer portion of Applicant's sensor (Fig. 1B), it is clear that the transducers are quite different. The Stasz transducer has a film covering over a layer of metallization, a flexible piezoelectric/pyroelectric film (PVDF), another layer of metallization, and finally a layer of adhesive material. In contrast, the sensor of Applicant shown in Fig. 1B, is a rectangular strip of flexible film to which a resistive material e.g., a resistive ink is applied to a limited area of the non-conductive flexible film.

Attached to this Response is a Declaration by William C. Zimlich, Jr. As can be seen from the *Curriculum Vitae* attached to Mr. Zimlich's Declaration, Mr. Zimlich has over 24 years of experience in research and development, product development, and manufacturing of various devices including medical devices and in particular, hand-held electrodynamic aerosolization devices. Over the course of his career, Mr. Zimlich has gained working knowledge of electronic assemblies through the development of video imaging systems, CPUs, keyboards, power supplies, robotic systems, drug delivery devices and other microprocessor based products and opto-mechanical devices.

As is evidenced by his *Curriculum Vitae*, Mr. Zimlich is "one skilled in this art". Based on his education and years of experience, it is his opinion that the Stasz reference does not disclose each and every element of Applicant's claimed invention. This opinion is based on the following differences between the invention of Applicant described in Claim 1 and the invention described and claimed in the Stasz reference. In particular, he notes the following differences:

1. Claim 1 of Lipp describes a sensor which contains a non-conductive flexible substrate. The flexible substrate disclosed by the Stasz reference is a conductive, "dynamic" film substrate which has both pyroelectric and piezoelectric properties and which produces a voltage output due to changes in temperature.

2. The non-conductive flexible substrate of Applicant's invention does not exhibit piezoelectric or pyroelectric properties as is required of the flexible film substrate of the Stasz reference.

3. Claim 1 of Lipp requires at least one "flexible lead" (16) connecting the substrate (13) to a mounting portion (18) of the sensor. The flexible lead (16), and the mounting portion (18) are areas of the non-conductive film substrate (13). The flexible substrate and the

flexible lead are displaceable in the presence of a stream of moving gas or liquid causing a flexure of the resistive ink transducer (22) and changing the electrical value of the transducer. These elements of Claim 1 of Lipp are not described or claimed in the Stasz reference.

4. A critical element of the sensor described in the Stasz patent, requires areas of "metallization" (18 and 20) to be present on both sides of the pyroelectric/piezoelectric film. These areas of metallization act as electrodes to conduct the low frequency voltage developed by the polyvinylidene fluoride film (PVDF) transducer due to changes in temperature to the circuit means. The sensor described in Claim 1 of Lipp does not contain any areas of metallization.

As is demonstrated herein and as supported by the Declaration of William Zimlich who is one skilled in this art, the invention disclosed by Stasz does not disclose to one of ordinary skill in this art all of the elements and limitations of Applicants claimed invention; accordingly, the Stasz reference does "anticipate" Applicant's claimed invention within the meaning of 35 USC §102(b).

IV. Conclusion

Based on the amendments and arguments made herein, it is respectfully asserted that Examiner's rejections have been overcome and that this application is in condition for allowance. Examiner is respectfully requested to withdraw all rejections and to issue a Notice of Allowance. If there are any questions regarding these amendments and remarks, Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

By: Patricia A. Coburn

Name: Patricia A. Coburn

Date: October 23, 2008

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